§ 127.615 Fires.

In the marine transfer area, the operator shall ensure that there are no fires when there is LNG present.

§ 127.617 Hotwork.

The operator shall ensure that no person conducts welding, torch cutting, or other hotwork unless that person has a permit from the COTP.

Subpart H—Security

§ 127.701 Security on existing facilities.

The operator shall ensure that any security procedure and arrangement on existing facilities, that were in use when LNG transfer operations were last conducted, be continued and maintained, or upgraded, whenever LNG transfer operations are conducted.

§ 127.703 Access to the marine transfer area.

The operator shall ensure that—

(a) Access to the marine transfer area from the shoreside and the waterside is limited to—

(1) Personnel who work at the facility including persons assigned for transfer operations, vessel personnel, and delivery and service personnel in the course of their business;

(2) Coast Guard personnel; and

(3) Other persons authorized by the operator; and

(b) No person is allowed into the marine transfer area unless that person is identified by a facility-issued identification card or other identification card displaying his or her photograph, or is an escorted visitor displaying an identifying badge.

§ 127.705 Security systems.

The operator shall ensure that security patrols of the marine transfer area are conducted once every hour, or that a manned television monitoring system is used, to detect—

(a) Unauthorized personnel;

(b) Fires; and

(c) LNG releases.

§ 127.707 Security personnel.

The operator shall ensure that no person is assigned security patrol duty unless that person has been instructed on security violation procedures.

§ 127.709 Protective enclosures.

The following must be within a fence or wall that prevents trespassing:

(a) Impounding spaces.

(b) Control rooms and stations.

(c) Electrical power sources.

§ 127.711 Communications.

The marine transfer area must have a means of direct communications between the security patrol and other operating or security personnel on duty on the facility.

Dated: September 3, 1987.

J.W. Kime,

Rear Admiral, U.S. Coast Guard Chief, Office of Marine Safety, Security and Environmental Protection.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 799

[OPTS-42084C; FRL-3325-1]

Commercial Hexane and Methycyclopentane; Test Rules

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: Pursuant to section 4(a) of the Toxic Substances Control Act (TSCA), EPA is issuing a final test rule requiring manufacturers and processors of commercial hexane to perform testing for subchronic toxicity, oncogenicity, reproductive toxicity, developmental toxicity, mutagencity, neurotoxicity, and inhalation and dermal pharmacokinetics and is terminating rulemaking under TSCA section 4(a) for subchronic toxicity, neurotoxicity, and inhalation and dermal pharmacokinetics testing of methylcyclopentane (MCP; CAS No. 96-37-7). Both actions follow EPA's proposed rule of May 15, 1986.

DATES: In accordance with 40 CFR 23.5, this rule shall be promulgated for purposes of judicial review at 1 p.m. eastern ("daylight" or "standard" as appropriate) time on February 19, 1988. This rule shall become effective on March 21, 1988. The incorporation by reference in the rule is approved by the Director of the Federal Register as of March 21, 1988.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Rm. E-543, 401 M St., SW., Washington, DC 20460 (202-554-1404).

SUPPLEMENTARY INFORMATION: EPA is issuing a final test rule under section 4(a) of TSCA to require health effects testing of commercial hexane. This test rule is being promulgated under 40 CFR 799.2155. EPA also is terminating rulemaking under section 4(a) of TSCA for MCP because EPA believes testing of MCP is not necessary at this time.

I. Introduction

A. Test Rule Development Under TSCA

This document is part of the overall implementation of section 4 of TSCA (Pub. L. 94-469, 90 Stat. 2003 *et seq.*; 15 U.S.C. 2601 *et seq.*), which contains authority for EPA to require development of data relevant to assessing the risks to health and the environment posed by exposure to particular chemical substances or mixtures.

Under section 4(a) of TSCA, EPA must require testing of a chemical substance or mixture to develop appropriate health or environmental data if the Administrator makes certain findings as described in TSCA under section 4(a)(1)(A) or (B). Detailed discussions of the statutory section 4 findings are provided in the Agency's first and second proposed test rules which were published in the **Federal Register** of July 18, 1980 (45 FR 48524) and June 5, 1981 (46 FR 30300).

B. Regulatory History

As published in the **Federal Register** of May 21, 1985 (50 FR 20930), the Interagency Testing Committee (ITC) designated MCP for priority consideration for health effects testing, including neurotoxicity, cardiotoxicity, oncogenicity, genotoxicity, teratogenicity, and reproductive effects. The Agency responded to the ITC's recommendations for MCP by publishing in the **Federal Register** of May 15, 1986 (51 FR 17854) a proposed rule for neurotoxicity (schedule-controlled operant behavior, neuropathology, functional observation battery, motor activity, and developmental neurotoxicity screen), subchronic toxicity, and inhalation and dermal pharmacokinetics (absorption, distribution, metabolism, and excretion) testing of MCP. The Agency also proposed acute and subchronic toxicity, oncogenicity, reproductive toxicity, developmental toxicity, mutagencity, neurotoxicity (schedule-controlled operant behavior, neuropathology, functional observation battery, and motor activity), and inhalation and dermal pharmacokinetics (absorption, distribution, metabolism, and excertion) testing for commercial hexane. The proposal contained information on chemical profiles, production, uses, human exposure, and health effects of MCP and commercial hexane; discussed ongoing testing of *n*-hexane and its metabolites; discussed EPA's TSCA section 4(a) findings; described the proposed tests, the test standards, and the test substances to be used; specified

who would be required to conduct the proposed testing; specified reporting requirements for data to be developed under the rule; discussed enforcement provisions; and presented issues for comment. On June 27, 1986 (51 FR 23440), EPA published corrections to the proposed rule.

Pursuant to a request by the American Petroleum Institute (API), EPA issued a notice (51 FR 26170; July 21, 1986) extending the comment period for an additional 60 days to September 15, 1986. API contended in its request that the composition of the commercial hexane identified in the proposed rule did not conform to the range of commercial hexanes in current production and commerce. The extension of time was granted to allow additional time for API and its member companies to develop a more representative definition of commercial hexane and to assist in determining manufacturers and processors subject to the rule.

On October 7, 1986, EPA held a public meeting to hear and discuss oral comments presented on various aspects of the proposed rule. The transcript of this meeting is part of the rulemaking record. Most of the discussion at this meeting focussed on whether testing both MCP and commercial hexane is necessary and on data submitted by API relating to the need for testing and the composition of the test substance.

II. Response to Public Comment

Written comments were submitted on behalf of industries and trade associations by the Exxon Co., U.S.A. (Exxon), the American Petroleum Institute (API), and the American Industrial Health Council (AIHC) and on behalf of public interest groups by the National Network to Prevent Birth Defects (NNPBD), the American Psychological Association (APA), and the Center for Science in the Public Interest (CSPI). These comments, as well as oral presentations made at the public meeting, dealt with the regulatory and legal authority of the Agency to make TSCA section 4 findings, the scientific rationale of the proposed testing, and the test methodologies. After the public meeting, the Agency, through its contractor, Syracuse Research Corp. (SRC), conducted a second literature review of commercial hexane. The Agency reevaluated these data and addressed all issues and comments, including additional comments submitted by API and APA after the close of the comment period and the public meeting. These comments have been addressed at length in a document entitled "Response to Public Comment on Methylcyclopentane and Commercial Hexane" and hereinafter called the "technical support document," which is part of the public record for this rulemaking (Ref. 1). Because of the number and the complexity of the comments as well as the length of the Agency's response to them, EPA is providing in this notice an overview of major concerns, a discussion of the issues raised in the proposed rule, and an explanation of changes in the final rule based on an analysis of the comments. The reader is referred to the technical support document (Ref. 1) for a more detailed discussion.

A. Overview of Industry's Major Comments and EPA's Response

1. Comment: *Data on commercial hexane for all endpoints are adequate.* The Agency requested comment on the availability of published and unpublished studies on commercial hexane A which would adequately describe its potential to cause any of the effects for which EPA had proposed testing (refer to the proposal for the definition of commercial hexane A, 51 FR 17864; May 15, 1986). EPA had a specific interest in obtaining data on the proposed test substance, commercial hexane A, because data (Ref. 2) available at the time of the proposal indicated that this type of hexane was responsible for the largest amount of human exposures and contained the largest amount of MCP. API clarified this matter with additional information and addressed all types of commercial hexanes in its comments (Refs. 3, 4 and 5). Therefore, the Agency has been able to evaluate the availability of health effects data related to all types of commercial hexane, rather than a specific type of commercial hexane.

In response to the issue of the availability of studies to characterize commercial hexane's health effects in humans, API (Ref. 3) and Exxon (Ref. 6) contended that there were sufficient data on commercial hexane to characterize all of the effects for which testing was proposed. They contended that existing studies of commercial hexane, mixtures of C_6 hydrocarbons, and individual components of commercial hexane provide adequate data from which to assess the potential health hazards from exposure to commercial hexane products. In support of this contention, API (Ref. 3) provided a review of the scientific data on commercial hexane and submitted a single-generation inhalation reproductive effects study which was completed after publication of the proposal. API (Ref. 3) and Exxon (Ref. 6) further contended that evaluation of these studies indicates that the proposed testing would not provide additional information relevant to assessing the risk from exposure to commercial hexane and that testing commercial hexane under TSCA section 4 is unnecessary.

The Agency reviewed the data provided in response to the proposal as well as those obtained from a literature review and concurs that the data are adequate to predict the acute toxicity of commercial hexane exposure to humans. However, the Agency has concluded that the data are inadequate to assess the risk of commercial hexane exposure to humans for all other health effects endpoints required by this rule.

Concerning the adequacy of health effects studies other than acute toxicity, industry commenters contend that the *n*-hexane component of the commercial hexane mixture is the driving variable in the hazard characterization of the mixture. For instance, Exxon (Ref. 6) stated that commercial hexane produces toxic responses which can be accounted for by its *n*-hexane content. In addition, in its supplemental comments, API (Ref. 4) claimed that EPA failed to consider all available information on commercial hexane and its constituents and that the data provide ample information to assess the adverse effects of exposure to commercial hexane. API, therefore, contended that a finding of data insufficiency could not be sustained.

EPA disagrees with the assumption that *n*-hexane is the only component of the mixture possessing potentially adverse toxicological properties and that commercial hexane will behave similarly to *n*-hexane. While EPA acknowledges the wealth of data on *n*-hexane, it is not willing to rely solely on those data to evaluate the health effects of the mixture at this time. Not only are the effects of the other constituents of commercial hexane unknown, but the interaction of *n*-hexane with the other components of commercial hexane is unknown. Moreover, these data also do not include all health effects endpoints required by this rule due to the widespread exposure to commercial hexane. Consequently, EPA believes that the data are inadequate to characterize the toxicity for health effects of commercial hexane other than for acute toxicity and that testing is necessary for the additional health endpoints. Industry comments on these data have been reviewed at length in the technical support document (Ref. 1). The following discussion is a brief overview of industry comments on data adequacy and modifications to the proposed

health effects testing in response to those comments:

a. *Acute toxicity.* EPA's initial evaluation indicated that there were no adequate acute toxicity data on commercial hexane. Specifically, there is no LC_{50} for commercial hexane. API (Refs. 3 and 4) commented that acute studies of commercial hexane show no mortality at 5 mg/1, the limit test in the TSCA test guidelines, and that testing to determine an LC_{50} is not necessary for chemicals whose acute toxicity is in excess of the limit test.

API (Ref. 3) and Exxon (Ref. 6) cited acute toxicity studies by Hine and Zuidema (Ref. 7) and Lazarew (Ref. 8) which reported exposures in animals between 39,000 and 73,000 ppm. They also cited API's single-generation inhalation reproductive effects study (Ref. 3, Att. I) in which no gross effects were observed at 1,500 ppm in rats exposed to commercial hexane for 6 hours per day, 7 days per week for 100 days. Exxon stated that API's study (Ref. 3, Att. I), although a subchronic study, demonstrated that rats could be exposed repeatedly to levels exceeding the EPA acute inhalation toxicity limit dose of 5 mg/1 without producing morbidity or mortality. Both API and Exxon also pointed out that not only was acute toxicity testing to determine an LC_{50} unnecessary, it was also dangerous because to produce mortality, it would be necessary to exceed commercial hexane's lower explosive limit (LEL) of approximately 11,000 ppm.

Having reviewed these studies along with additional acute studies, the Agency believes that requiring additional acute inhalation toxicity testing to determine an LC_{50} of commercial hexane will provide little additional information which will assist in characterizing the potential health risks to humans for several reasons: (1) While the studies cited by API and Exxon have deficiencies in that the test material was not always fully described, the concentration of the test material was not always determined, and the descriptions of the effects of exposure were minimal, taken together, they provide a strong indication that the LC_{50} for commercial hexane is above 30,000 ppm; and (2) it appears that the LC_{50} for commercial hexane is within its explosive limits (11,000 to 75,000 ppm), which would not only make testing hazardous but would also preclude such high occupational exposures because of the explosive hazard. Consequently, EPA believes that it can make reasonable predictions about the acute toxicity of commercial hexane, has concluded tha the proposed requirement for acute inhalation toxicity testing (section 798.1150) to determine an LC_{50} is unnecessary, and has not included it in the final rule. However, EPA is retaining the requirement for schedule-controlled operant behavior testing (section 798.6500) under acute neurotoxicity testing because of concerns for effects on the rate and pattern of behavioral responses to commercial hexane.

To accommodate API's concerns on the safety of the testing, however, EPA has modified all of the remaining required tests so that the highest dose should not exceed the lower explosive limit of commercial hexane.

b. *Subchronic toxicity.* EPA proposed that a subchronic inhalation toxicity test be conducted on commercial hexane because existing data submitted by Phillips Petroleum (Ref. 9, Att. IV) was considered inadequate to characterize the nephrotoxicity of commercial hexane. API (Refs. 3 and 4) commented that existing data are adequate to predict the subchronic toxicity of commercial hexane. API (Refs. 3 and 4) and Exxon (Ref. 6) maintain that the study submitted by Phillips Petroleum adequately addresses the nephrotoxicity of commercial hexane and cited additional studies that further characterize the subchronic toxicity of commercial hexane or similar products. API (Ref. 3) believes that existing data demonstrate that the components of commercial hexane produce hydrocarbon-induced nephrotoxicity and that it would be a waste of resources to require a 90-day study to demonstrate an adverse effect already known. However, Exxon (Ref. 6) believes that the induction of nephropathy in male rats has no human clinical significance.

EPA disagrees that these data adequately address the potential for commercial hexane to be nephrotoxic. These data are inadequate because each study had experimental limitations, such as short duration, which compromised the interpretation of the findings (Ref. 1). In addition, EPA believes that a comprehensive inhalation subchronic toxicity test for commercial hexane is necessary to determine whether endpoints other than neurotoxicity might be more sensitive indicators of commercial hexane's toxicity at lower doses. Consequently, EPA has retained the proposed requirement for subchronic toxicity teting by inhalation. For consistency with other test rules, the final rule requires that the animals be dosed for 6 hours per day, 5 days per week for 90 days.

c. *Oncogenicity.* API (Refs. 3 and 4) commented that the data are adequate to reasonably predict the oncogenicity of commercial hexane and that a chronic bioassay would not add significant information for a quantitative risk assessment. In support of this contention, API (Ref. 3) cited two negative cancer studies on *n*-hexane.

EPA disagrees with API that the studies conducted by Sice (Ref. 11) and by Ranadive et al. (Ref. 12) fulfill the requirement of an inhalation oncogenicity test on commercial hexane. These studies exposed animals dermally to only one dose level of *n*-hexane, tested only one species and one sex, and contained too few animals. Consequently, EPA has retained the requirement for oncogenicity testing. The Agency believes that existing data are inadequate and that testing is necessary to determine the oncogenic risk of exposure to commercial hexane.

d. *Reproductive toxicity.* API (Refs. 3 and 4) commented that its single-generation inhalation reproductive effects study of commercial hexane (Ref. 2, Att. I) is adequate for substances which do not bioaccumulate. EPA has reviewed this study and believes that it is inadequate to assess the potential reproductive toxicity of commercial hexane (Ref. 13). The highest dose level was too low, and the sample size for histopathological evaluation of male reproductive organs was too small, to assess any adverse effect. In addition, the paper by Christian (Ref. 14) which API used to support its contention that single-generation studies are sufficient to assess a chemical's reproductive toxicity requiring two-generation studies should be altered. EPA believes that a well-conducted, two-generation study is necessary to assess commercial hexane's potential reproductive effects and has retained the proposed requirement for a two-generation reproductive effects study of commercial hexane.

Concerning animal strains, EPA recommends the use of Sprague-Dawley rats in both the developmental and the reproductive toxicity studies for the following reasons: API's single-generation inhalation reproductive effects study (Ref. 3, Att. I) was conducted on commercial hexane in Sprague-Dawley rats; the data base on Sprague-Dawley rats for these two health effects is much greater than for Fischer 344 rats; and, in general, Fischer 344 rats are not good breeders and, therefore, are not a good choice of strain in developmental and reproductive effects testing.

e. *Developmental toxicity.* API (Refs. 3 and 4) commented that its single-generation reproductive effects study of commercial hexane (Ref. 3. Att. I) had a satellite teratology component in rats which was adequate to predict the developmental toxicity of commercial hexane. EPA, however, believes that this study was inadequate to assess the potential developmental toxicity of commercial hexane (Ref. 13). The study was inadequate because the highest dose level failed to elicit significant signs of maternal toxicity. In addition, only animals in the control and highest dose groups were analyzed, and restrictions in sample size of pregnant animals hampered meaningful interpretation of results. EPA believes that a well-conducted developmental toxicity study in two species, such as rats and rabbits, will provide needed data on commercial hexane's potential developmental toxicity and has retained the proposed requirement for a developmental toxicity study of commercial hexane.

f. *Mutagenicity.* API (Refs. 3 and 4) and Exxon (Ref. 6) commented that the data are adequate to evaluate the genotoxicity of the components of commercial hexane and are therefore adequate to predict its potential mutagenicity, and that further testing would provide no further information and would be a waste of resources. They further commented that the weight of available evidence suggests that commercial hexane poses no risk for the induction of heritable genetic effects.

EPA considers the data presented by API (Ref. 3) as suggestive of the effects anticipated for commercial hexane but not adequate to fully characterize its genotoxicity. Because the components of commercial hexane have undergone only limited genotoxicity testing and because the data base is insufficient to extrapolate from the individual components to the commercial hexane mixture. EPA disagrees with industry and has retained the proposed requirement for mutagenicity testing.

API (Ref. 3) requested an additional 4 weeks to conduct the *in vivo* mutagenicity testing because of the difficulty in administering the test substance by inhalation and an additional six months to conduct the pharmacokinetics testing because of its complexity. For upper-tier mutagenicity testing triggered by lower-tier test results in particular, API requested that the deadline for the final reports be based on the test trigger dates rather than on the effective date of the final rule.

Since issuing the proposal, EPA has reviewed the time periods that it will specify for conducting these health effects tests. For consistency with the other TSCA section 4 final test rules recently promulgated and pursuant to API's request, the final reporting requirements have been modified to allow additional time for conducting the following tests: *Salmonella typhimurium* assay—4 additional months; gene mutation in mammalian cells in culture—5 additional months; *in vitro* cytogenetics assay—5 additional months; *in vivo* cytogenetics assay—7 additional months; rodent dominant lethal assay—4 additional months; heritable translocation assay—1 additional month; and schedule-controlled operant behavior, functional observation battery, motor activity, and neuropathology—3 additional months. Although an acute test, the final report of schedule-controlled operant behavior has been increased to 15 months to coincide with the final reports of the 3 subchronic neurotoxicity tests.

EPA proposed a tiered testing approach to evaluate whether commercial hexane elicits heritable gene mutations. Positive results in certain lower-tier tests would trigger the requirement for conducting a mouse visible specific locus (MVSL) test. EPA believes that the MVSL is necessary, when certain lower-tier tests are positive, to establish definitively whether a substance is capable of eliciting heritable gene mutations. Under the approach proposed, EPA would consider the positive results in lower-tier tests in a public program review, together with other relevant information, during which interested persons would be able to give their views to the Agency. If, after the review, EPA determined that the MVSL was still appropriate, EPA would notify the test sponsors by letter or Federal Register notice that they must conduct the test. If EPA determined that the test was no longer necessary, EPA would propose to amend the rule to delete the test requirement.

The final test rule for commercial hexane includes requirements to conduct the lower-tier tests for gene mutations. However, EPA is not promulgating the requirement for the MVSL for commercial hexane at this time. EPA had based its proposal to require the MVSL, in part, on information and assumptions about the cost of conducting the test and the availability of laboratories capable of performing the test. The information and assumptions have since proven to be incorrect. Accordingly, EPA is in the process of reexamining the MVSL requirement for this test rule as well as those for other chemical substances. In particular EPA is reviewing whether any laboratories are available to perform the MVSL for industry in accordance with the TSCA Good Laboratory Practice Standards at 40 CFR Part 792 and the cost of such testing. EPA is also reviewing possible alternative tests to the MVSL for which costs may be lower or laboratory availability may be more certain.

Once EPA completes its evaluation of this additional information, EPA will publish a notice in the **Federal Register** concerning the MVSL for commercial hexane and other substances subject to TSCA section 4 test rules. This notice will provide up-to-date information on the cost of MVSL testing, availability of laboratories to perform the MVSL, and possible alternative tests to the MVSL together with their costs and laboratory availability. The notice will also address EPA's intentions about any changes to the MVSL requirements in the various test rules and will provide an opportunity for public comment. If, after this exercise, EPA concludes that the MVSL is still appropriate for commercial hexane, EPA will amend this final test rule for commercial hexane to add the MVSL requirements with any appropriate modifications.

Concerning upper-tier mutagenicity tests triggered by lower-tier test results, EPA agrees with API that the deadlines for the final reports should be based on the trigger dates rather than on the effective date of the final rule. For consistency with other TSCA section 4 final test rules, the heritable translocation assay is triggered from the date of notification that testing is required rather than from the effective date of the final rule. Public participation in this program review will be in the form of written public comments or a public meeting. Before the last tier mutagenicity testing is to begin, EPA will hold a public program review if the results of the previous tier tests are positive. If, after review of public comment, no change in the test sequence is deemed necessary, EPA will provide formal notification to the test sponsor that the final tier tests must be conducted. If, however, EPA believes that additional testing is no longer warranted as a result of review of earlier test results, public comments, scientific judgment, and other appropriate factors, EPA will issue a proposed amendment to rescind these requirements. Refer to the table in Unit IV.B. concerning other reporting requirements for commercial hexane testing.

g. *Neurotoxicity testing.* API (Refs. 3 and 4) and Exxon (Ref. 6) commented

that there are sufficient data on the neurotoxicity of *n*-hexane and other C_6 hydrocarbons to reasonably predict the neurotoxic potential of commercial hexane. They believe that the two API studies submitted by Phillips Petroleum (Ref. 9, Atts. II and III) adequately demonstrate that *n*-hexane is the only neurotoxic C_6 hydrocarbon.

EPA disagrees with API and Exxon that these studies adequately address the potential neurotoxicity of commercial hexane. In addition, EPA believes that these studies do not provide sufficient data to quantitatively predict the risk of human exposure to commercial hexane because it is necessary to test at the maximum tolerated doses (MTD) without exceeding the lower explosive limit of commercial hexane to determine whether C_6 hydrocarbons other than *n*-hexane are neurotoxic or potentiate the toxicity of *n*-hexane.

Consequently, EPA has retained the requirement for neurotoxicity testing. Existing studies neither address the potential neurotoxicity of commercial hexane nor provide sufficient data to predict human risk.

h. *Pharmacokinetics.* API (Refs. 3 and 4) commented that studies of *n*-hexane in animals and in humans have characterized its absorption, distribution, metabolism, and excretion and that *n*-hexane does not alter the pharmacokinetic behavior of the other C_6 constituents. API also stated that it has an ongoing study in rats to evaluate the absorption of hydrocarbon vapors. EPA disagrees with API and believes that neither existing data nor the ongoing API study will be adequate to characterize the absorption, distribution, metabolism, or excretion of commercial hexane.

However, following an internal review of the proposed pharmacokinetics guideline, EPA determined that there were sections which would preclude obtaining meaningful data (e.g., the absence of intravenous dosing). Consequently, EPA will repropose a revised test standard and reporting requirements for inhalation and dermal pharmacokinetics at a later date.

Concerning API's comments on the difficulty of conducting pharmacokinetics testing of the commercial hexane mixture, EPA agrees with API that isotopically labeling all components of commercial hexane would be burdensome. When EPA reproposes new methodology for the pharmacokinetics test standard, it will propose labeling MCP in commercial hexane and separately labeling *n*-hexane in commercial hexane as suggested by API (Ref. 3).

2. Comment: *Inaccurate characterization of production and use led to an undocumented finding of significant human exposure to commercial hexane.* While API (Ref. 3) recognizes the information-gathering function of TSCA section 4, it questioned the accuracy of EPA's characterization of commercial hexane's production and use in the proposal. API believes that the Agency's characterization of commercial hexane neither reflects current manufacturing processes nor accurately describes the composition of the majority of current commercial hexane products.

EPA has evaluated the data submitted by API and has concluded, nevertheless, that there may be widespread exposure to commercial hexane from its production and uses. EPA has made reasonable assumptions based on standard engineering principles that human exposure to commercial hexane will occur during its manufacture, processing, use, and disposal. The Agency's assumptions for exposure to commercial hexane were based upon its high volatility, high production, high number of potentially exposed workers, and potential consumer exposure through paints and solvents. The Agency believes that these assumptions support a finding under TSCA section 4(a)(1)(B) that there may be substantial human exposure to commercial hexane.

3. Comment: *Information on commercial hexane and similar C_6 products, including MCP, makes testing unnecessary.* API (Ref. 3) and Exxon (Ref. 6) believe that EPA failed to identify all relevant data on C_6 isomers. Exxon (Ref. 6) believes that existing data and experience with C_6-containing substances other than commercial hexane, e.g., motor fuels, are relevant to determining the effects of human exposure to C_6 isomers. Exxon further contends that a full analysis of all C_6 exposure data may allow a finding that exposure to C_6 isomers does not present an unreasonable health risk. Exxon also claimed that the data on commercial hexane are sufficient for a quantitative risk assessment and therefore for regulatory action under TSCA section 6. Because Exxon believes that EPA can make at this time a determination that there is no risk to human health or the environment, it believes that further testing under TSCA section 4 is unwarranted and requests that the proposal be withdrawn.

While there may be information on commercial hexane and similar C_6 products, EPA believes that such information is inadequate to evaluate the potential health effects from exposure to commercial hexane or similar C_6 products for all but acute effects, as discussed in Unit II.A.1 above. Other endpoints have not been tested adequately. In addition, the test methodologies specified in this rule are more sensitive and the tests more refined than were those used for existing studies. EPA believes that additional data are necessary to determine whether exposure to commercial hexane does not present an unreasonable risk of injury to human health.

B. Response to Issues Raised in the Proposed Rule

1. Issue: *How should commercial hexane be defined so as to determine who is subject to the rule?* EPA proposed to test a type of commercial hexane with the greatest MCP content to which humans are most likely exposed and at the same time assumed that this material would be representative of commercial hexanes produced by major manufacturers. API (Refs. 3 and 18), however, contended that this characterization neither reflected current manufacturing practices nor applied to a significant portion of currently produced commercial hexanes. Consequently, the Agency granted an additional 60 days for API and its member companies to develop a more representative definition of commercial hexane and to better determine manufacturers and processors subject to the rule. From the results of an API survey indicating that *n*-hexane comprised 40 to 86 liquid volume percent and MCP 5 to 15 liquid volume percent of commercial hexanes, API (Ref. 3) provided an alternative definition of commercial hexane, developed by the American Society for Testing and Materials (ASTM), ASTM D 1836 (Ref. 16).

Accordingly, EPA has revised the definition of commercial hexane to contain a minimum of 40 rather than 50 liquid volume percent *n*-hexane and a minimum of 5 liquid volume percent MCP and otherwise conform to the specifications prescribed in ASTM D 1836. API (Ref. 3) stated that this revised definition includes all identified products manufactured and used as commercial hexane. EPA interprets this to mean that the revised definition includes the products produced by all known manufacturers and processors of commercial hexane, making all of them subject to this test rule.

2. Issue: *Which substance should be tested to characterize the toxicity of commercial hexane: commercial hexane A or n-hexane-free C_6 isomers?* EPA proposed that the test substance consist

of commercial hexane A, or solvent grade, derived from the fractionation of straight-run gasoline, consisting of no more than 64 liquid volume percent *n*-hexane and no less than 19 liquid volume percent MCP. The Agency believed that maximizing the MCP content of commercial hexane would provide more useful test data. Pursuant to comments from API (Ref. 3), EPA has deleted reference to the feedstock origin and the grade of commercial hexane in the final rule and defers to API's analysis that commercial hexane made according to the specifications of ASTM D 1836 is the one to which there is the greatest exposure. However, to assure that the full potential for MCP's toxicity might be expressed, EPA has modified API's recommendation by specifying that not less than 10 liquid volume percent MCP be present in the test substance. The Agency believes that this modification will accommodate API's concerns and yet will represent a worst-case exposure to MCP and C_6 isomers other than *n*-hexane.

3. Issue: *Should the subchronic test standards be modified to follow the 22 hours/day, 7 days/week, 6-month dosing regimen of the API and Egan et al. studies?* When comparing the toxicity of *n*-hexane with and without other C_6 isomers, Egan et al. (Ref. 23) and API (Ref. 9, Atts. II and III) used a dosing regimen of 22 hours/day, 7 days/week for 6 months. When determining the subchronic toxicity of *n*-hexane in rats, Cavender et al. (Ref. 24) of the Chemical Industry Institute of Technology (CIIT) used 6 hours/day, 5 days/week for 6 months. The National Toxicology Program (NTP) currently is using a dosing regimen of 6 hours/day, 5 days/week for 6 months to determine the subchronic toxicity of *n*-hexane in mice. Unless anticipating exposure of humans to a substance is continuous, under TSCA section 4, EPA typically specifies a dosing regimen of 6 hours/day, 5 days/week for a 90-day period in a subchronic toxicity test. Because of the differences in dosing regimens, EPA requested comment on whether the dosing regimen should be increased from 6 hours/day for 5 days/week to 22 hours/day for 7 days/week.

At the public meeting, Bus (Ref. 5), in discussing the importance of duration of daily exposure to study design, stated that for compounds such as *n*-hexane, 22-hour per day rather than 6-hour per day exposure durations give a more rapid onset at lower exposure concentrations.

The Agency has studied these comments but disagrees that the duration of exposure should be increased for subchronic toxicity testing of commercial hexane for several reasons. First, continuous inhalation exposure designs do not approximate conditions of human exposure to commercial hexane and therefore do not adequately define threshold levels of toxicity under expected exposure conditions. Compared to 6-hour per day, 5-day per week exposures, continuous exposure experiments use an exposure scenario not comparable to either workplace or consumer exposures. Second, the protocol required by the Agency is designed to mimic worker exposure, the population most likely to be exposed to commercial hexane. Third, the results from the study would be comparable to those from other subchronic testing required under TSCA section 4 by EPA for chemicals in the workplace. Chemicals primarily found in the home or other institutions in which humans may be continuously exposed would serve as better candidates for the continuous exposure regimen. Finally, continuous exposures do not permit a recovery period, potentially overloading metabolic systems.

An additional comment on the exposure regimen used in existing studies was provided by Wood (Ref. 25). Wood raised concerns that there could have been flaws in the exposure generation methods used by Egan et al. (Ref. 23) resulting in lower actual doses than specified in the experimental design. Wood contends that because of potential variations in exposure concentrations, Egan et al. were probably unsuccessful in maintaining the sustained exposure levels necessary for the identification of neurotoxicity comparable to that produced by *n*-hexane.

Consequently, because the composition of the atmosphere containing the test substance could change, the Agency recommends that there be sufficient monitoring of the concentrations of the test substance and its components to ensure that the composition of the atmosphere containing the test substance and its components do not vary significantly throughout the exposure period of each test.

III. Decision to Terminate Rulemaking for Health Effects Testing of MCP

Under TSCA section 4(a), EPA had proposed to require testing of MCP. Although isolated MCP has not been sold in the U.S. since 1982 (Ref. 9), the proposal noted that MCP is a substantial component of various hexane-containing refinery streams and products whose manufacture, processing, and use result in extensive, albeit indirect, exposure of workers, consumers, and the general population. EPA also recognized that MCP was isolated in the past and could be isolated either at present or in the future. In addition, the Agency's proposed findings for health effects testing of MCP were based upon positive hazard evidence to support a "may present an unreasonable risk" finding under section 4(a)(1)(A) for neurotoxicity (nerve functional deficits) and subchronic toxicity (nephrotoxicity) as well as potential exposure of 38,000 workers to MCP. Furthermore, in an EPA survey, MCP was detected in breast milk samples. However, because at this time MCP is not isolated and because all current exposure results from exposure to mixtures containing MCP, the Agency believes that testing MCP as a discrete substance is unnecessary and is terminating rulemaking under TSCA section 4(a) at this time.

The Agency reached this decision after reevaluating existing data in conjunction with comments from industry in response to the proposed rule. Consequently, the Agency has decided to terminate rulemaking on the health effects testing of MCP for the following reasons:

1. MCP currently is not isolated; it is not manufactured for direct sales; and its production as a discrete substance has not been reported under the TSCA Inventory Update Rule (Ref. 17). Furthermore, from industry's comments on the proposed test rule, the Agency does not anticipate any future isolated production of MCP.

2. There is a naphtha stream consisting of benzene and 60 to 80 percent MCP that is used to make cyclohexane. Although there may be the potential for greater exposure to MCP by virtue of its greater content in the naphtha stream compared to its content in commercial hexane, the process is limited to one manufacturer with only a few potentially exposed workers. Furthermore, this patented process is not expected to proliferate to other manufacturers after expiration of the patent in 12 years.

3. Because exposure to MCP almost always involves exposure to other C_6 isomers, and because the highest MCP concentration to which workers and consumers are typically exposed is in commercial hexane, EPA agrees with industry comments that commercial hexane is a more appropriate test substance than MCP. EPA believes that it is better first to test commercial hexane rather than each of its C_6 components individually. If health effects are positive for commercia

hexane, then EPA may consider testing the C_6 components individually.

IV. Final Test Rule for Commercial Hexane

A. Findings

EPA is basing its final health effects testing requirements for commercial hexane on the authority of section 4(a)(1)(B) of TSCA.

Under section 4(a)(1)(B), EPA finds that commercial hexane is produced in substantial quantities and that there is or may be substantial human exposure from its manufacture, processing, distribution in commerce, and use. Approximately 500 million pounds of commercial hexane were produced in 1985 (Ref. 26). In addition, according to the National Occupational Exposure Survey of 1985 (NOES), 83,000 workers are estimated to have actual exposure to hexane solvents. Of these, 12,576 are women (Ref. 19). Commercial hexanes are used as components of lacquers, printing inks, and adhesives, and as seed oil extractants (Ref. 2). Such uses may result in widespread exposure to workers and consumers.

While EPA believes that there may be substantial human exposure to C_6 hydrocarbons in gasoline, EPA is not considering exposure to the C_6 fraction through exposure to gasoline as part of its basis for finding substantial human exposure to commercial hexane. The Agency believes that exposures associated with the manufacture and processing of commercial hexanes and use of solvents containing significant concentrations of C_6 isomers provide sufficient basis for a finding of substantial human exposure for commercial hexane under TSCA section 4(a)(1)(B)(i).

In the proposed rule, the Agency requested comments as to whether there existed studies in the published and unpublished literature that would adequately describe the potential health effects of commercial hexane. EPA's initial evaluation had indicated that there were inadequate data to predict commercial hexane's acute and subchronic toxicities, oncogenicity, reproductive toxicity, developmental toxicity, mutagenicity, neurotoxicity, and pharmacokinetics in humans exposed from its manufacture, processing, distribution in commerce, and use.

To determine the adequacy of health effects data on commercial hexane, EPA reviewed data submitted in response to the proposal by API (Refs. 3 and 4) and by Exxon (Ref. 6) as well as data from the scientific literature. Consequently, EPA finds that there are sufficient data by inhalation exposure to reasonably determine or predict the acute effects of human exposure to commercial hexane resulting from its manufacture, processing, distribution in commerce, and use. Therefore, the Agency has concluded that there is no need to require acute toxicity testing of commercial hexane. However, EPA finds that there are insufficient data to reasonably determine or predict the subchronic toxicity, the oncogenicity, the reproductive toxicity, the developmental toxicity, the mutagenicity, the neurotoxicity, and the pharmacokinetics in humans exposed to commercial hexane from its manufacture, processing, distribution in commerce, and use. EPA believes that the data resulting from these test requirements will be relevant to a determination that the manufacture, processing, distribution in commerce, and use of commercial hexane does or does not present an unreasonable risk of injury to human health. For these reasons, EPA finds that testing is necessary to develop such data.

B. Required Testing, Test Standards, and Reporting Requirements

On the basis of these findings, the Agency is requiring that health effects testing be conducted for commercial hexane in accordance with specific test guidelines set forth in 40 CFR Part 798 as enumerated in the following table.

REQUIRED TESTING, TEST STANDARDS, AND REPORTING REQUIREMENTS FOR COMMERCIAL HEXANE

Test	40 CFR citation [1]	Reporting deadline for final report [2]	Number of interim (6-mo) reports required
Subchronic toxicity: Subchronic inhalation toxicity	§ 798.2450	15	2
Chronic toxicity: Oncogenicity	§ 798.3300	53	8
Specific organ/tissue toxicity:			
Reproduction and fertility effects	§ 798.4700	29	4
Inhalation developmental toxicity	§ 798.4350	12	1
Genetic toxicity:			
Gene Mutations:			
Salmonella typhimurium	§ 798.5265	8	0
Mammalian cells in culture	§ 798.5300	17	2
Drosophila sex-linked recessive lethal	§ 798.5275	24	3
Chromosomal Aberrations:			
In vitro cytogenetics	§ 798.5375	9	0
In vivo cytogenetics	§ 798.5385	19	3
Dominant lethal assay	§ 798.5450	28	4
Heritable translocation assay	§ 798.5460	[3] 25	4
Acute neurotoxicity: Schedule-controlled operant behavior	§ 798.6500	15	2
Subchronic neurotoxicity:			
Functional observation battery	§ 798.6050	15	2
Motor activity	§ 798.6200	15	2
Neuropathology	§ 798.6400	15	2

[1] As modified in § 799.2155.
[2] Number of months after the effective date of the final rule, except as indicated.
[3] Figure indicates the reporting deadline, in months, calculated from the date of notification of the test sponsor by certified letter or FEDERAL REGISTER notice that, following public program review of all of the then existing data for commerical hexane, the Agency has determined that the required testing must be performed.

Revisions to these guidelines were proposed in the **Federal Register** of January 14, 1986 (51 FR 1522) and were promulgated in the **Federal Register** of May 20, 1987 (52 FR 19056).

The Agency is requiring that the above-referenced TSCA health effects test guidelines be the test standards for the purposes of the required tests for commercial hexane. The TSCA test guidelines for health effects testing

specify generally accepted minimum conditions for determining the health effects of substances like commercial hexane to which humans are expected to be exposed. The Agency believes that these test methods reflect the current state-of-the-art science and minimum requirements for the conduct of these tests. However, because of the high volatility and explosive properties of commercial hexane and because human exposure occurs primarily by inhalation, EPA is requiring chemical-specific modifications to all of the required test methods that take into account these factors.

All data developed under this rule must be reported in accordance with TSCA Good Laboratory Practice (GLP) Standards which appear in 40 CFR Part 792.

In accordance with 40 CFR Part 790 under single-phase rulemaking procedures, test sponsors are required to submit individual study plans at least 45 days before the initiation of each test.

EPA is required by TSCA section 4(b)(1)(C) to specify the time period during which persons subject to a test rule must submit test data. The rule specifies the reporting requirements for each of the required test standards for commercial hexane. Interim progress reports for certain studies must be provided to the Agency at 6-month intervals as indicated in the rule until the final report has been submitted to EPA.

TSCA section 14(b) governs Agency disclosure of all test data submitted pursuant to section 4 of TSCA. Upon receipt of data required by this rule, the Agency will publish a notice of receipt in the Federal Register as required by section 4(d).

Persons who export a chemical substance or mixture which is subject to a section 4 test rule are subject to the export reporting requirements of section 12(b) of TSCA. Final regulations interpreting the requirements of section 12(b) are in 40 CFR Part 707. In brief, as of the effective date of this test rule, an exporter of commercial hexane must report to EPA the first export or intended export of commercial hexane to a particular country in a calendar year. EPA will notify the foreign country concerning the test rule for the chemical.

C. Test Substance

Concerning the definition of commercial hexane so as to determine who is subject to the rule, the rule defines commercial hexane as containing a minimum of 40 liquid volume percent *n*-hexane, a minimum of 5 liquid volume percent MCP, and otherwise conforming to the specifications prescribed in ASTM D 1836. The requirement that commercial hexane contain at least 5 liquid volume percent MCP remains the same as in the proposed rule because API's survey indicated commercial hexanes currently produced contain at least 5 liquid volume percent MCP. This definition determines which manufacturers and processors are subject to the rule.

Concerning the composition of the actual test substance, EPA is specifying that the test substance contain no more than 40 liquid volume percent *n*-hexane, no less than 10 liquid volume percent MCP, and otherwise conform to the specifications prescribed in ASTM D 1836. EPA believes that the commercial hexane being tested should be defined in this manner to assure that the full potential for MCP toxicity may be expressed. In addition, such a test substance will be similar to the test material used in API's single-generation inhalation reproductive effects study (Ref. 3, Att. I). By specifying a commercial hexane test substance with no more than 40 percent *n*-hexane and no less than 10 percent MCP, EPA believes that the test substance will represent a worst-case exposure to MCP and C_6 isomers other than *n*-hexane and provide a complement to existing data on *n*-hexane.

D. Persons Required to Test

Section 4(b)(3)(B) specifies that the activities for which EPA makes section 4(a) findings (manufacture, processing, distribution in commerce, use, and/or disposal) determine who bears the responsibility for testing a chemical. Manufacturers and persons who intend to manufacture the chemical are required to test if the findings are based on manufacturing ("manufacture" is defined in section 3(7) of TSCA to include "import"). Processors and persons who intend to process the chemical are required to test if the findings are based on processing. Manufacturers and processors and persons who intend to manufacture and process the chemical are required to test if the exposure giving rise to the potential risk occur during distribution in commerce, use, or disposal of the chemical.

Because EPA has found that manufacturing, processing, distribution in commerce, and use of commercial hexane give rise to exposure that may lead to an unreasonable risk, persons who manufacture or process, or who intend to manufacture or process, commercial hexane, other than as an impurity, at any time from the effective date of the final test rule to the end of the reimbursement period are subject to the testing requirements contained in this final rule. The end of the reimbursement period will be 5 years after the last report is submitted or an amount of time equal to that which was required to develop data, if more than 5 years after the submission of the last final report required under the test rule.

Because TSCA contains provisions to avoid duplicative testing, not every person subject to this rule must individually conduct testing. Section 4(b)(3)(A) of TSCA provides that EPA may permit two or more manufacturers or processors who are subject to the rule to designate one such person or a qualified third person to conduct the tests and submit data on their behalf. Section 4(c) provides that any person required to test may apply to EPA for an exemption from the requirement. EPA promulgated procedures for applying for TSCA section 4(c) exemptions in 40 CFR Part 790.

Manufacturers (including importers) subject to this rule are required to submit either a letter of intent to perform testing or an exemption application within 30 days after the effective date of the final test rule. The required procedures for submitting such letters and applications are described in 40 CFR Part 790. Although EPA has not identified any individuals who manufacture commercial hexane as a byproduct, such persons will be subject to the requirements of this test rule.

Processors subject to this rule, unless they are also manufacturers, will not be required to submit letters of intent or exemption applications, or to conduct testing, unless manufacturers fail to submit notices of intent to test or later fail to sponsor the required tests. The Agency expects that the manufacturers will pass an appropriate portion of the costs of testing on to processors through the pricing of their products or reimbursement mechanisms. If manufacturers perform all the required tests, processors will be granted exemptions automatically. If manufacturers fail to submit notices of intent to test or fail to sponsor all the required tests, the Agency will publish a separate notice in the Federal Register to notify processors to respond; this procedure is described in 40 CFR Part 790.

EPA is not requiring the submission of equivalence data as a condition for exemption from the required testing for commercial hexane. As noted in Unit II.B., EPA is requiring a specific type of commercial hexane for testing and believes that testing such a substance will allow reasonable prediction of the potential of various commercial hexane

products to cause the effects to be studied. For the purposes of this rule, EPA assumes that all commercial hexanes are equivalent to the commercial hexane test substance.

Manufacturers and processors subject to this test rule must comply with the test rule development and exemption procedures in 40 CFR Part 790 for single-phase rulemaking.

E. Enforcement Provisions

The Agency considers failure to comply with any aspect of a section 4 rule to be a violation of section 15 of TSCA. Section 15(1) of TSCA makes it unlawful for any person to fail or refuse to comply with any rule or order issued under section 4. Section 15(3) of TSCA makes it unlawful for any person to fail or refuse to: (1) Establish or maintain records, (2) submit reports, notices, or other information, or (3) permit access to or copying of records required by TSCA or any regulation or rule issued under TSCA.

Additionally, TSCA section 15(4) makes it unlawful for any person to fail or refuse to permit entry or inspection as required by TSCA section 11. Section 11 applies to any "establishment, facility, or other premises in which chemical substances or mixtures are manufactured, processed, stored, or held before or after their distribution in commerce * * *" The Agency considers a testing facility to be a place where the chemical is held or stored and, therefore, subject to inspection. Laboratory inspections and data audits will be conducted periodically in accordance with the authority and procedures outlined in TSCA section 11 by duly designated representatives of the EPA for the purpose of determining compliance with the final rule for commercial hexane. These inspections may be conducted for purposes which include verification that testing has begun, schedules are being met, and reports accurately reflect the underlying raw data, interpretations, and evaluations, and to determine compliance with TSCA GLP standards and the test standards established in the rule.

EPA's authority to inspect a testing facility also derives from section 4(b)(1) of TSCA, which directs EPA to promulgate standards for the development of test data. These standards are defined in section 3(12)(B) of TSCA to include those requirements necessary to assure that data developed under testing rules are reliable and adequate, and to include such other requirements as are necessary to provide such assurance. The Agency maintains that laboratory inspections are necessary to provide this assurance.

Violators of TSCA are subject to criminal and civil liability. Persons who submit materially misleading or false information in connection with the requirement of any provision of this rule may be subject to penalties which may be calculated as if they never submitted their data. Under the penalty provisions of section 16 of TSCA, any person who violates section 15 of TSCA could be subject to a civil penalty of up to $25,000 for each violation with each day of operation in violation constituting a separate violation. This provision would be applicable primarily to manufacturers that fail to submit a letter of intent or an exemption request and that continue manufacturing after the deadlines for such submissions. This provision would also apply to processors that fail to submit a letter of intent or an exemption application and continue processing after the Agency has notified them of their obligation to submit such documents (see 40 CFR 790.28(b)). Knowing or willful violations could lead to the imposition of criminal penalties of up to $25,000 for each day of violation and imprisonment for up to 1 year. In determining the amount of penalty, EPA will take into account the seriousness of the violation and the degree of culpability of the violator as well as all the other factors listed in TSCA section 16. Other remedies are available to EPA under section 17 of TSCA, such as seeking an injunction to restrain violations of TSCA section 4.

Individuals as well as corporations could be subject to enforcement actions. Sections 15 and 16 of TSCA apply to "any person" who violates provisions of TSCA. EPA may, at its discretion, proceed against individuals as well as companies themselves. In particular, this includes individuals who report false information or who cause it to be reported. In addition, the submission of false, fictitious, or fraudulent statements is a violation under 18 U.S.C. 1001.

V. Economic Analysis of Final Rule

To assess the economic impact of this rule, EPA has prepared an economic analysis (Ref. 26) that evaluates the potential for significant economic impacts on the industry as a result of the required testing. The economic analysis estimates the costs of conducting the required testing and evaluates the potential for significant adverse economic impact as a result of these test costs by examining four market characteristics of commercial hexane: (1) Price sensitivity of demand; (2) industry cost charactertistics; (3) industry structure; and (4) market expectations. Because there was not any indication of adverse impact, no further economic analysis was performed. However, had the first level of analysis indicated a potential for significant economic impact, a more comprehensive and detailed analysis would have been conducted to more precisely predict the magnitude and distribution of the expected impact.

Testing costs for the final rule for commercial hexane are estimated to range from $2.2 to $2.9 million. To predict the financial decision-making practices of manufacturing firms, these costs have been annualized. Annualized costs are compared with annual revenue as an indication of potential impact. The annualized costs represent equivalent constant costs which would have to be recouped each year of the payback period in order to finance the testing expenditure in the first year.

The annualized test costs (using a cost of capital of 7 percent over a period of 15 years) range from $250,000 to $320,000. Based on 1985 production of 480 million pounds, the unit test costs range from $0.0005 to $0.0007 per pound. In relation to the selling price of $0.20 per pound for commercial hexane, these costs are equivalent to 0.26 to 0.33 percent of price.

Based on these costs and the uses of commercial hexane, the economic analysis indicates that the potential for significant adverse economic impact as a result of this test rule is low. This conclusion is based on the following observations:

1. The estimated unit test costs are low, 0.33 percent of the current price in the upper-bound case.

2. The overall demand for commercial hexane appears relatively inelastic with respect to price in all of its major uses.

Refer to the economic analysis for a complete discussion of test cost estimation and the potential for economic impact resulting from these costs.

VI. Availability of Test Facilities and Personnel

Section 4(b)(1) of TSCA requires EPA to consider "* * * the reasonably foreseeable availability of the facilities and personnel needed to perform the testing required under the rule." Therefore, EPA conducted a study to assess the availability of test facilities and personnel to handle the additional demand for testing services created by section 4 test rules. Copies of the study, Chemical Testing Industry: Profile of Toxicological Testing, can be obtained through the National Technical Information Service (NTIS), 5285 Port

Royal Road, Springfield, VA 22161 (PB 82-140773).

AIHC (Ref. 10) commented that the Agency did not adequately address in the proposal the availability of facilities or personnel to conduct the neurotoxicity testing required by this rule. EPA has reviewed the availability of contract laboratory facilities to conduct the neurotoxicity testing requirements (Ref. 20) and believes that facilities will be made available for conducting these tests. The laboratory review indicates that few laboratories are currently conducting these tests according to TSCA test guidelines and TSCA GLP standards. However, the barriers faced by testing laboratories to gear-up for these barriers are not formidable. Laboratories will have to invest in testing equipment and personnel training, but EPA believes that these investments will be recovered as the neurotoxicity testing program under TSCA section 4 continues. EPA's expectations of laboratory availability were borne out under the testing requirements of the C_9 aromatic hydrocarbon fraction test rule (50 FR 20675; May17, 1985). Pursuant to that rule, the manufacturers were able to contract with a laboratory to conduct the testing according to TSCA test guidelines and TSCA GLP standards.

VII. Rulemaking Record

EPA has established a record for this rulemaking, (docket number OPTS-42084C). This record contains the basic information considered by the Agency in developing this rule and appropriate Federal Register notices.

This record includes the following information:

A. Supporting Documentation

(1) Federal Register notices pertaining to this rule consisting of:

(a) Notice containing the ITC designation of MCP to the Priority List (50 FR 20930; May 21, 1985).

(b) Rules requiring TSCA section 8(a) and 8(d) reporting on MCP (50 FR 20909; May 21, 1985).

(c) Notice of final rule on EPA's TSCA Good Laboratory Practice Standards (48 FR 53922; November 29, 1983).

(d) Notice of interim final rule on single-phase test rule development and exemption procedures (50 FR 20652; May 17, 1985).

(e) Notice of final rule on data reimbursement policy and procedures (48 FR 31786; July 11, 1983).

(f) Notice of proposed rule on TSCA test guidelines revisions (51 FR 1522; January 14, 1986).

(g) Notice of final rule revising TSCA test guidelines (52 FR 19056; May 20, 1987).

(h) Notice of EPA's proposed test rule on MCP and commercial hexane (51 FR 17854; May 15, 1986).

(i) Notice of corrections to the proposed rule (51 FR 23440; June 27, 1986).

(j) Notice of extension of comment period on the proposed rule (51 FR 26170; July 21, 1986).

(k) Notice of EPA's final rule on the C_9 aromatic hydrocarbon fraction (50 FR 20662; May 17, 1985).

(2) Support documents consisting of:

(a) Technical support document for proposed rule.

(b) Economic impact analysis of NPRM for MCP and commercial hexane.

(3) TSCA test guidelines cited as test standards for this rule.

(4) Communications consisting of:

(a) Written public comments and letters.

(b) Contact reports of telephone conversations.

(5) Reports—published and unpublished factual materials, including: Chemical Testing Industry: Profile of Toxicological Testing (October 1981).

B. References

(1) US Environmental Protection Agency (USEPA). "Response to public comment on MCP and commercial hexane" (December 23, 1987).

(2) Grayson, M., ed. *Kirk-Othmer Encyclopedia of Chemical Technology*, 3rd ed., Volume 12, New York: John Wiley & Sons. pp. 926-937 (1980).

(3) American Petroleum Institute (API). Letter from Steven M. Swanson, Director, Health and Environmental Affairs Department, to USEPA, transmitting comments on the MCP and commercial hexane proposed test rules (September 15, 1986).

(4) API. Letter from Steven M. Swanson, Director, Health and Environmental Affairs Department, to Gary E. Timm, Chief, Test Rules Development Branch, USEPA, transmitting supplemental submission in response to issues raised by USEPA at the public meeting (January 9, 1987).

(5) USEPA. Transcript of proceedings of the public meeting on proposed test rules for MCP and commercial hexane (October 7, 1986).

(6) Exxon Company, USA. Letter from Edward DiCorcia, Vice President, Refining Department, to USEPA, transmitting comments on the MCP and commercial hexane proposed test rules (September 11, 1986).

(7) Hine, C.H., and Zuidema, H.H. "Toxicological properties of hydrocarbon solvents." *Industrial Medicine* 39: 39-44 (1970).

(8) Lazarew, N.W. "Effects of *n*-hexane in man and animals." *Archives of Experimental Pathology and Pharmacology* 143: 223-233 (1929).

(9) Phillips Petroleum Company. Letter from John J. Moon, Manager, Environment and Consumer Protection, to the Office of Toxic Substances, USEPA, transmitting comments on the ITC's 16th Report and three toxicity studies (June 28, 1985).

(10) American Industrial Health Council, Inc. (AIHC). Letter from John L. O'Donoghue, Chairman, AIHC Neurotoxicology Subcommittee, to USEPA, transmitting comments on the MCP and commercial hexane proposed test rules (August 13, 1986).

(11) Sice, J. "Tumor-promoting activity of *n*-alkanes an 1-alkanols." *Toxicology and Applied Pharmacology* 9: 70-74 (1966).

(12) Ranadive, K.J., Gothoskar, S.V., and Texabwala, B.U. "Carcinogenicity of contaminants in indigenous edible oils." *International Journal on Cancer* 10: 652-666 (1972).

(13) USEPA. Internal memorandum from Susan Vogt, Acting Director, Health and Environmental Review Division to Gary E. Timm, Chief, Test Rules Development Branch, transmitting a review by Elaine Z. Francis of API's single-generation reproductive effects study of commercial hexane (April 13, 1987).

(14) Christian, M.S. "A critical review of multigenerational studies." *Journal of the American College of Toxicology* 5: 161-180 (1986).

(15) No reference.

(16) American Society for Testing and Materials (ASTM). "Standard specification for commercial hexanes." *1986 Annual Book of ASTM Standards: Petroleum Products and Lubricants*, ASTM D 1836-83, pp. 966-967 (1986).

(17) USEPA. Internal memorandum from Denise Devoe, Chief, Confidential Data Branch, to Gary E. Timm, Chief, Test Rules Development Branch, concerning the Chemical Update System (May 14, 1987).

(18) API. Letter from William F. O'Keefe, Vice President, to Edwin F. Tinsworth, Acting Director, Office of Toxic Substances, USEPA, requesting an extension of the comment period on the MCP and commercial hexane proposed test rules (June 24, 1986).

(19) National Institute for Occupational Safety and Health (NIOSH). National Occupational Exposure Survey Data Base (NOES). Washington, DC. US Department of Health and Human Services Computer Printout (June 1, 1985).

(20) Mathtech Inc. "Evaluation of TSCA guidelines for neurotoxicity testing: Impact of increased testing requirements." Prepared for Regulatory Impacts Branch, USEPA (April 14, 1987).

(21) No reference.

(22) No reference.

(23) Egan, G., Spencer, P., Schaumburg, H., Murray, K.J., Bischoff, M., and Scala, R. "*n*-Hexane-'free' hexane mixture fails to produce nervous system damage." *Neurotoxicology* 2: 515-524 (1980).

(24) Cavender, F.L., Casey, H.W., Salem, H., Graham, D.G., Swenberg, J.A., and Gralla, E.J. "A 13-week vapor inhalation study of *n*-hexane in rats with emphasis on neurotoxic effects." *Fundamental and Applied Toxicology* 4: 191-201 (1984).

(25) American Psychological Association (APA). Letter from Ronald W. Wood, Chairman, Neurobehavioral Toxicity Test Standards Committee, to USEPA, transmitting comments on the MCP and commercial hexane proposed test rules (November 6, 1986).

(26) ICF Inc. "Analysis of economic impacts for a toxicity test of commercial hexane." Prepared for Regulatory Impacts Branch, USEPA (July 1987).

The record is available for inspection from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays, in Rm. NE-G004, 401 M St., SW., Washington, DC 20460.

VIII. Other Regulatory Requirements

A. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a rule is "Major" and therefore subject to the requirement of a Regulatory Impact Analysis. EPA has determined that this test rule is not major because it does not meet any of the criteria set forth in section 1(b) of the Order, i.e., it will not have an annual effect on the economy of at least $100 million, will not cause a major increase in costs or prices, and will not have a significant adverse effect on competition or the ability of US enterprises to compete with foreign enterprises. The economic analysis of the testing of commercial hexane is discussed in Unit V.

This rule was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291. Any written comments from OMB to EPA, and any EPA response to those comments, are included in the rulemaking record.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (15 U.S.C. 601 *et seq.*, Pub. L. 96-354, September 19, 1980), EPA is certifying that this test rule will not have a significant impact on a substantial number of small businesses because: (1) They are not likely to perform testing themselves, or to participate in the organization of the testing effort; (2) they will experience only very minor costs, if any, in securing exemption from testing requirements, and (3) they are unlikely to be affected by reimbursement requirements.

C. Paperwork Reduction Act

OMB has approved the information collection requirements contained in this final rule under the provisions of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*, Pub. L. 96-511, December 11, 1980), and has assigned OMB control number 2070-0033.

List of Subjects in 40 CFR Part 799

Chemicals, Environmental protection, Hazardous substances, Incorporation by reference, Laboratories, Recordkeeping and reporting requirements, Testing.

Dated: January 28, 1988.

J.A. Moore,

Assistant Administrator for Pesticides and Toxic Substances.

Therefore, 40 CFR Part 799 is amended as follows:

PART 799—[AMENDED]

1. The authority citation for Part 799 continues to read as follows:

Authority: 15 U.S.C. 2603, 2611, 2625.

2. By adding § 799.2155 to read as follows:

§ 799.2155 Commercial hexane.

(a) *Identification of test substance.* (1) "Commercial hexane," for purposes of this section, is a product obtained from crude oil, natural gas liquids, or petroleum refinery processing in accordance with the American Society for Testing and Materials Designation D 1836-83 (ASTM D 1836), consists primarily of six-carbon alkanes or cycloalkanes, and contains at least 40 liquid volume percent *n*-hexane (CAS No. 110-54-3) and at least 5 liquid volume percent methylcyclopentane (MCP; CAS No. 96-37-7). ASTM D 1836, formally entitled "Standard Specification for Commercial Hexanes," is published in *1986 Annual Book of ASTM Standards: Petroleum Products and Lubricants*, ASTM D 1836-83, pp. 966-967, 1986, is incorporated by reference, and is available for public inspection at the Office of the Federal Register, Room. 8301, 1100 L Street NW., Washington, DC. This incorporation by reference was approved by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 522(a) and 1 CFR Part 51. This material is incorporated as it exists on the date of approval, and a notice of any change in this material will be published in the **Federal Register**. Copies of the incorporated material may be obtained from the Document Control Officer (TS-793), Office of Toxic Substances, EPA, Room. NE-G004, 401 M Street SW., Washington, DC 20460.

(2) The commercial hexane test substance, for purposes of this section, is a product which conforms to the specifications of ASTM D 1836 and contains no more than 40 liquid volume percent *n*-hexane and no less than 10 liquid volume percent MCP.

(b) *Persons required to submit study plans, conduct tests, and submit data.* All persons who manufacture (including import) or process or intend to manufacture or process commercial hexane, as defined in paragraph (a)(1) of this section and order than as an impurity, from the effective date of the final rule to the end of the reimbursement period shall submit letters of intent to conduct testing, submit study plans, conduct tests in accordance with Part 792 of this chapter, and submit data, or submit exemption applications, as specified in this section, Subpart A of this part, and Part 790 of this chapter for single-phase rulemaking. Persons who manufacture commercial hexane as a byproduct are covered by the requirements of this section.

(c) *Health effects testing*—(1) *Subchronic inhalation toxicity*—(i) *Required testing.* (A) A subchronic inhalation toxicity test shall be conducted with commercial hexane in accordance with § 798.2450 of this chapter except for the provisions in paragraphs (d)(4)(ii) and (5) of § 798.2450.

(B) For the purposes of this section, the following provisions also apply:

(*1*) *High dose level.* The highest concentration should result in toxic effects but neither produce an incidence of fatalities which would prevent a meaningful evaluation nor exceed the lower explosive limit of commercial hexane.

(*2*) *Exposure conditions.* Animals shall be dosed for 6 hours/day, 5 days/week for 90 days.

(ii) *Reporting requirements.* (A) The subchronic inhalation toxicity test shall be completed and the final report submitted to EPA within 15 months of the effective date of the final rule.

(B) Interim progress reports shall be submitted to EPA for the subchronic inhalation toxcity test at 6-month intervals beginning 6 months after the effective date of the final rule, until the final report is submitted to EPA.

(2) *Oncogenicity*—(i) *Required testing.* (A) An oncogenicity test shall be conducted with commercial hexane in accordance with § 798.3300 of this chapter except for the provisions in paragraphs (b)(3)(ii) and (6) of § 798.3300.

(B) For the purposes of this section, the following provisions also apply:

(*1*) *High dose level.* The high dose level should elicit signs of minimal toxicity without substantially altering the normal life span and should not exceed the lower explosive limit of commercial hexane.

(*2*) *Administration of test substance.* Animals shall be exposed to commercial hexane by inhalation.

(ii) *Reporting requirements.* (A) The oncogenicity test shall be completed and the final report submitted to EPA within 53 months of the effective date of the final rule.

(B) Interim progress reports shall be submitted to EPA for the oncogenicity test at 6-month intervals beginning 6 months after the effective date of the final rule, until the final report is submitted to EPA.

(3) *Reproduction and fertility effects.*—(i) *Required testing.* (A) A reproduction and fertility effects test shall be conducted with commercial hexane in accordance with § 798.4700 of this chapter except for the provisions in paragraphs (c)(3)(ii) and (5) of § 798.4700.

(B) For the purposes of this section, the following provisions also apply:

(*1*) *High dose level.* The highest dose level should induce toxicity but not high levels of mortality in the parental (P) animals. In addition, the highest dose level should not exceed the lower explosive limit of commercial hexane.

(*2*) *Administration of test substance.* Animals shall be exposed to commercial hexane by inhalation.

(ii) *Reporting requirements.* (A) The reproduction and fertility effects test shall be completed and the final report submitted to EPA within 29 months of the effective date of the final rule.

(B) Interim progress reports shall be submitted to EPA for the reproduction and fertility effects test at 6-month intervals beginning 6 months after the effective date of the final rule, until the final report is submitted to EPA.

(4) *Inhalation developmental toxicity*—(i) *Required testing.* (A) An inhalation developmental toxicity test shall be conducted with commercial hexane in accordance with § 795.4350 of this chapter except for the provisions in paragraph (e)(3)(iv) of § 798.4350.

(B) For the purposes of this section, the following provisions also apply:

(*1*) *High dose level.* Unless limited by the physical/chemical nature or biological properties of the test substance, the highest concentration level shall induce some overt maternal toxicity such as reduced body weight or body weight gain, but not more than 10 percent maternal deaths. In addition, the highest dose level should not exceed the lower explosive limit of commercial hexane.

(*2*) [Reserved]

(ii) *Reporting requirements.* (A) The inhalation developmental toxicity test shall be completed and the final report submitted to EPA within 12 months of the effective date of the final rule.

(B) Interim progress reports shall be submitted to EPA for the inhalation developmental toxicity test at 6-month intervals beginning 6 months after the effective date of the final rule, until the final report is submitted to EPA.

(5) *Mutagenic effects—gene mutations*—(i) *Required testing.* (A)(*1*) A *Salmonella typhimurium* reverse mutation assay shall be conducted with commercial hexane in accordance with § 798.5265 of this chapter except for the provisions in paragraphs (d)(4) and (e) of § 798.5265.

(*2*) For the purposes of this section, the following provisions also apply:

(*i*) *Metabolic activation.* Bacteria shall be exposed to commercial hexane both in the presence and absence of an appropriate metabolic activation system.

(*ii*) *Test performance.* The assay shall be performed using the desiccator method described as follows: The agar overlay plates shall be placed uncovered in a 9-liter desiccator. A volume of the liquid test substance shall be added to the glass Petri dish suspended beneath the porcelain shelf of the desiccator. The highest exposure concentration should not result in a vapor concentration which exceeds the lower explosive limit of commerical hexane. A magnetic stirring bar to serve as a fan to assure rapid and even distribution of the vapor shall be placed on the bottom of the inside of the desiccator. The desiccator shall be placed on a magnetic stirrer within a 37°C room or chamber for 7 to 10 hours. The plates shall then be removed, their lids replaced, followed by incubation for an additional 40 hours at 37°C before counting. An appropriate selective medium with an adequate overlay agar shall be used. All plating should be done in at least triplicate.

(B)(*1*) A gene mutation test in mammalian cells shall be conducted with commercial hexane in accordance with § 798.5300 of this chapter except for the provisions in paragraphs (d)(3)(ii) and (4) of § 798.5300 if the results from the *Salmonella typhimurium* test conducted pursuant to paragraph (c)(5)(i)(A) of this section are negative.

(*2*) For the purposes of this section, the following provisions also apply:

(*i*) *Cell growth and maintenance.* Treatment flasks shall be incubated on a rocker panel to insure maximum contact between the cells and the test agent. Incubation shall be at 37°C for 18 hours for experiments without metabolic activation and for 5 hours for experiments with activation. Each flask shall be closed with a cap with a rubber septum. Headspace samples shall be taken at the beginning and the end of exposure period and analyzed to determine the amount of test substance in each flask. The vapor concentration should not exceed the lower explosive limit of commercial hexane.

(*ii*) [Reserved]

(C) (*1*) A sex-linked recessive lethal test in *Drosophila melanogaster* shall be conducted with commercial hexane in accordance with § 798.5275 of this chapter except for the provisions in paragraphs (d)(5) (ii) and (iii) of § 798.5275, unless the results of both the *Salmonella typhimurium* test conducted pursuant to paragraph (c)(5)(i)(A) of this section and the mammalian cells in the culture gene mutation test conducted pursuant to paragraph (c)(5)(i)(B) of this section, if required, are negative.

(*2*) For the purposes of this section, the following provisions also apply:

(*i*) *Dose levels.* For the initial assessment of mutagenicity, it is sufficient to test a single dose of the test substance for screening purposes. This dose should be the maximum tolerated dose, or that which produces some indication of toxicity or shall be the highest dose attainable and should not exceed the lower explosive limit of commercial hexane. For dose-response purposes, at least three additional dose levels should be used.

(*ii*) *Route of administration.* The route of administration shall be by exposure to commercial hexane vapors.

(D) [Reserved]

(*ii*) *Reporting requirements.* (A) The gene mutation tests shall be completed and final reports submitted to EPA as follows:

(*1*) The *Salmonella typhimurium* reverse mutation assay within 8 months of the effective date of the final rule.

(*2*) The gene mutation in mammalian cells assay within 17 months of the effective date of the final rule.

(*3*) The sex-linked recessive-lethal test in *Drosophila melanogaster* within 24 months of the effective date of the final rule.

(*3*) [Reserved]

(B) Interim progress reports for each test shall be submitted to EPA for the gene mutation in mammalian cells assay and *Drosophila* sex-linked recessive lethal test at 6-month intervals beginning 6 months after the effective date of the final rule, until the applicable final report is submitted to EPA.

(C) [Reserved]

(6) *Mutagenic effects—chromosomal aberrations*— (i) *Required testing.* (A)(*1*) An *in vitro* cytogenetics test shall be conducted with commercial hexane in accordance with § 798.5375 of this chapter except for the provisions in paragraph (e)(3) of § 798.5375.

(*2*) For the purposes of this section, the following provisions also apply:

(*i*) *Treatment with test substance.* The test shall be performed using flasks flushed with commercial hexane vapors, then closed with a cap with a rubber

septum. The highest exposure concentration should not result in a vapor concentration which exceeds the lower explosive limit of commercial hexane.

(*ii*) [Reserved]

(B)(*1*) An *in vivo* cytogenetics test shall be conducted with commercial hexane in accordance with § 798.5385 of this chapter except for the provisions in paragraphs (d)(5) (ii), (iii) and (iv) of § 798.5385, if the *in vitro* test conducted pursuant to paragraph (c)(6)(i)(A) of this section is negative.

(*2*) For the purposes of this section, the following provisions also apply:

(*i*) *Dose levels.* For an initial assessment, one dose level of the test substance may be used, the dose being the maximum tolerated dose (to a maximum of 5,000 mg/kg), or that producing some indication of cytotoxicity (e.g., partial inhibition of mitosis), or shall be the highest dose attainable (to a maximum of 5,000 mg/kg) and should not exceed the lower explosive limit of commercial hexane. Additional dose levels may be used. For determination of dose-response, at least three dose levels should be used.

(*ii*) *Route of administration.* Animals shall be exposed to commercial hexane by inhalation.

(*iii*) *Treatment schedule.* The duration of exposure shall be for 6 hours per day for 5 consecutive days.

(C) (*1*) A dominant lethal assay shall be conducted with commercial hexane in accordance with § 798.5450 of this chapter except for the provisions in paragraphs (d)(5) (ii) and (iii) of § 798.5450, unless both the *in vitro* and *in vivo* cytogenetics tests conducted pursuant to paragraphs (c)(6)(i) (A) and (B) of this section are negative.

(*2*) For the purposes of this section, the following provisions also apply:

(*i*) *Dose levels.* Normally, three dose levels shall be used. The highest dose shall produce signs of toxicity (e.g., slightly reduced fertility and slightly reduced body weight). The highest dose should not exceed the lower explosive limit of commercial hexane. However, in an initial assessment of dominant lethality, a single high dose may be sufficient. Nontoxic substances shall be tested at 5 g/kg or, if this is not practicable, then at the highest dose attainable.

(*ii*) *Route of administration.* Animals shall be exposed to commercial hexane by inhalation.

(*iii*) *Treatment schedule.* The duration of exposure shall be for 6 hours per day for 5 consecutive days.

(D)(*1*) A heritable translocation test shall be conducted with commercial hexane in accordance with § 798.5460 of this chapter except for the provisions in paragraphs (d)(5) (ii) and (iii) of § 798.5460, if the results of the dominant lethal assay conducted pursuant to paragraph (c)(6)(i)(C) of this section are positive and if, after a public program review, EPA issues a Federal Register notice or sends a certified letter to the test sponsor specifying that the testing shall be initiated.

(*2*) For the purposes of this section, the following provisions also apply:

(*i*) *Dose levels.* At least two dose levels shall be used. The highest dose level shall result in toxic effects (which shall not produce an incidence of fatalities which would prevent a meaningful evaluation) or shall be the highest dose attainable or 5 g/kg body weight and should not exceed the lower explosive limit of commercial hexane.

(*ii*) *Route of administration.* Animals shall be exposed to commercial hexane by inhalation.

(*iii*) *Reporting requirements.* (A) The chromosomal aberration tests shall be completed and the final reports submitted to EPA as follows:

(*1*) The *in vitro* cytogenetics test within 9 months of the effective date of the final rule.

(*2*) The *in vivo* cytogenetics test within 19 months of the effective date of the final rule.

(*3*) The dominant lethal assay within 28 months of the effective date of the final rule.

(*4*) The heritable translocation test within 25 months of the date of EPA's notification of the test sponsor by certified letter or Federal Register notice that testing shall be initiated.

(B) Interim progress reports for each test shall be submitted to EPA for the *in vivo* cytogenetics and the dominant lethal assays at 6-month intervals beginning 6 months after the effective date of the final rule, until the applicable final report is submitted to EPA.

(C) Interim progress reports shall be submitted to EPA for the heritable translocation assay at 6-month intervals beginning 6 months after the date of EPA's notification of the test sponsor that testing shall be initiated, until the final report is submitted to EPA.

(*7*) *Neutrotoxicity*—(i) *Required testing.* (A)(*1*) A schedule-controlled operant behavior test shall be conducted with commercial hexane in accordance with § 798.6500 of this chapter except for the provisions in paragraphs (d)(5)(i), (6) and (7) of § 798.6500.

(*2*) For the purposes of this section, the following provisions also apply:

(*i*) *High dose level.* The highest dose shall produce clear behavioral effects or life-threatening toxicity. In addition, the highest dose should not exceed the lower explosive limit of commercial hexane.

(*ii*) *Duration and frequency of exposure.* Animals shall be dosed once for 4 to 6 hours.

(*iii*) *Route of administration.* Animals shall be exposed to commercial hexane by inhalation.

(B)(*1*) A functional observation battery shall be conducted with commercial hexane in accordance with § 798.6050 of this chapter except for the provisions in paragraphs (d)(4)(i), (5), and (6) of § 798.6050.

(*2*) For the purposes of this section, the following provisions also apply:

(*i*) *High dose level.* The highest dose shall produce clear behavioral effects or life-threatening toxicity. In addition, the highest dose should not exceed the lower explosive limit of commercial hexane.

(*ii*) *Duration and frequency of exposure.* Animals shall be dosed for 6 hours/day, 5 days/week for 90 days.

(*iii*) *Route of exposure.* Animals shall be exposed to commercial hexane by inhalation.

(C)(*1*) A motor activity test shall be conducted with commercial hexane in accordance with § 798.6200 of this chapter except for the provisions in paragraphs (d)(4)(i), (5), and (6) of § 798.6200.

(*2*) For the purposes of this section, the following provisions also apply:

(*i*) *High dose level.* The highest dose shall produce clear effects on motor activity of life-threatening toxicity. In addition, the highest dose should not exceed the lower explosive limit of commercial hexane.

(*ii*) *Duration and frequency of exposure.* Animals shall be dosed for 6 hours/day, 5 days/week for 90 days.

(*iii*) *Route of exposure.* Animals shall be exposed to commercial hexane by inhalation.

(D)(*1*) A neuropathology test shall be conducted with commercial hexane in accordance with § 798.6400 of this chapter except for the provisions in paragraphs (d)(4)(i), (5), and (6) of § 798.6400.

(*2*) For the purposes of this section, the following provisions also apply:

(*i*) *High dose level.* The highest dose shall produce clear behavior effects or life-threatening toxicity. In addition, the highest dose should not exceed the lower explosive limit of commercial hexane.

(*ii*) *Duration and frequency of exposure.* Animals shall be dosed for 6 hours/day, 5 days/week for 90 days.

(*iii*) *Route of exposure.* Animals shall be exposed to commercial hexane by inhalation.

(ii) *Reporting requirements.* (A) The schedule-controlled operant behavior, functional observation battery, motor activity, and neuropathology tests shall be completed and the final reports submitted to EPA within 15 months of the effective date of the final rule.

(B) Interim progress reports for each test shall be submitted to EPA for the schedule-controlled operant behavior, functional observation battery, motor activity, and neuropathology tests at 6-month intervals beginning 6 months after the effective date of the applicable final rule, until the applicable final report is submitted to EPA.

(8) [Reserved]

(d) *Effective date.* The effective date of the final rule for commercial hexane is March 21, 1988.

(Information collection requirements have been approved by the Office of Managment and Budget under control number 2070-0033)

[FR Doc. 88-2439 Filed 2-4-88; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Office of the Secretary

43 CFR Part 29

Trans-Alaska Pipeline Liability Fund

AGENCY: Department of the Interior, Office of the Secretary.

ACTION: Final rule.

SUMMARY: This final rule amends the regulations for supervision and administration of the Trans-Alaska Pipeline Liability Fund (Fund) provided for by section 204(c) of the Trans-Alaska Pipeline Authorization Act (Act). The final rule eliminates inconsistencies between the existing regulations and the Act, clarifies confusing language and deletes unnecessary provisions.

EFFECTIVE DATE: March 7, 1988.

FOR FURTHER INFORMATION CONTACT: Bruce Blanchard, Office of Environmental Project Review, Room 4256, Department of the Interior, Washington, DC 20240, telephone (202) 343-3891.

SUPPLEMENTARY INFORMATION: On June 29, 1987, the Department of the Interior published for comment in the **Federal Register** a proposed rule that would amend its regulations for supervision and administration of the Fund. This proposed rule was published in response to a petition from the Fund. The petition was published as part of the proposed rule. The petition and the preamble to the proposed rule described the bases for the proposed changes to the current regulations, and the Department's observations on the petition, respectively (52 FR 24181).

The Department of the Interior received three sets of comments from two sources. One commenter was the Environmental Protection Agency, which the Department of the Interior had specifically requested to comment (52 FR 24182). The other was the Fund, which on two separate occasions provided substantive comments and comments concerning typographical errors contained in the proposed rule.

A summary of the comments and the Department's responses to the comments follow.

1. Notification Requirements

EPA commented that the first sentence of proposed § 29.8(a) failed to make clear whether the discovery of an incident must be made by the person in charge of the vessel and whether the incident must involve the vessel. EPA then suggested language to clarify the meaning of the sentence. As the Department intended that the obligations of the person in charge of the vessel would begin as soon as he or she becomes aware of an incident involving his or her vessel, this comment has merit. Accordingly, the Department has revised the first sentence, although the specific language suggested by EPA has not been used.

EPA also suggested, concerning the same sentence, that the regulation specify that the notification of the incident be made to the National Response Center rather than the "Coast Guard." EPA's stated concern was that without the change a person in charge of a vessel might contact a Coast Guard unit rather than the National Response Center. As the Department's intent was that the person in charge of the vessel should contact the National Response Center, the EPA's suggestion is accepted with clarification to assure it is understood that the National Response Center is operated by the Coast Guard.

EPA also suggested that in the last sentence of proposed § 29.8(a) the citation to the Federal Water Pollution Control Act (FWPCA) be clarified, and that a reference be made to EPA's recently promulgated regulations implementing the notification requirements of the FWPCA. The citation clarification has been made. The Department also agrees to make reference to the EPA's notification requirements; the change is consistent with the Department's intent that the § 29.8 notification requirements are in addition to notification requirements under the FWCPA.

Finally, EPA suggested that in proposed § 29.8(b) the term "Coast Guard" be replaced with "National Response Center." This change has bee made. To be consistent with the other changes in § 29.8 the reference to "Coast Guard" in § 29.8(c)(1) has also been changed to "National Response Center." A conforming change has also been made to § 29.1(d).

2. Definitions

EPA comments that the use of the term "spill" in proposed § 29.8(c)(1) and (d) could cause confusion as the term "spill" is not defined in proposed § 29.1. EPA suggests that the term "incident", which is defined in proposed § 29.1, be used instead of "spill". The Department agrees that without some reference to "spill" in § 29.1 some confusion could arise. Accordingly, the Department is amending § 29.1(h) to indicate that "incident" and "spill" can be used interchangeably.

EPA also commented that proposed § 29.1(h) (definition of "incident") would limit incidents to instances where there is a "discharge of TAPS oil". The Department recognizes that section 204(c)(1) of the Trans-Alaska Pipeline Authorization Act applies to "discharges of oil" from a vessel carrying TAPS oil, and did not intend to change the statutory application. Accordingly, the Department has amended § 29.1(h) to indicate that an incident "means a discharge of oil from a vessel which is carrying TAPS oil loaded on that vessel. . . ."

The Fund questioned in two respects the basis for the Department's disagreement with the Fund's rationale for the deletion of proposed § 29.1(e)(7) (numbered as § 29.1(d)(7) prior to the promulgation of this final rule), found at 52 FR 24181-82. First, the Fund questions the Department's observation that the current regulation could be read as making loss of tax revenue an element of damages without a showing of proximate cause; the Fund notes that proximate cause must be shown for all damages under the Act. The Fund is correct; under the current regulations and as amended, any claim may be paid only upon a showing that the economic loss arises out of or results directly from an incident. See § 29.1(e).

The Fund also asserts the Department states incorrectly in the preamble to the proposed rule that loss of tax revenues may constitute damages. The Department disagrees with this comment. The Department's intent is only that if a claimant is able to demonstrate that any economic loss arises out of or results directly from an